Stat. 770, 774 (1974) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101–6.1015 (1990).

Dated: March 23, 1999.

Wendy M. Comes,

Executive Director.

[FR Doc. 99–7480 Filed 3–25–99; 8:45 am]

BILLING CODE 1610–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 20 and 21, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, Walker and Whetstone Rooms, Two Montgomery Village Ave, Gaithersburg, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857; 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the safety and efficacy of new drug application (NDA) 21–042 Vioxx™ (rofecoxib, Merck) for the treatment of acute or chronic signs and symptoms of osteoarthritis and the management of pain.

Procedure: On April 20, 1999, from 8 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 14, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 14, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On April 21, 1999, from 8 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C., app.2).

Dated: March 16, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–7362 Filed 3–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Changing Times; Clinical Trial Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), Southeast Region, is announcing the following meeting: ''Changing Times: Clinical Trial Regulations, Clinical Investigators and IRB's Learning to Cope.'' The topic to be discussed is FDA regulatory requirements for the conduct of clinical studies and practical issues such as how clinical investigators and Institutional Review Boards can cope with the regulatory process, how to prepare for a data audit, what to expect during an inspection, and how to get current information from FDA.

Date and Time: The meeting will be held on Friday, April 30, 1999, from 8 a.m. to 6 p.m.

Location: The meeting will be held at the Veterans Administration Medical Center Auditorium (2d floor), 1201 NW. 25th St., Miami, FL 33125.

Contact: Luz I. Collado, Food and Drug Administration, HFR–SE2575, P.O. Box 59–2256, Miami, FL 33159, 305–526–2800, ext. 926, or Brunilda Torres, Food and Drug Administration, Florida District, HFR–SE250, 407–475–4718, FAX 407–475–4768.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to Gloria Allington, Director, University of Miami School of Medicine, Division of Continuing Medical Education, 1500 NW. 12th Ave., Miami, FL 33136, 305–243–6716, FAX 305–243–5613. Attendance will be limited to the first 200 applicants, therefore, interested parties are encouraged to register early. A $100 registration fee is being charged by the University of Miami School of Medicine to help cover costs of materials, breakfast, box lunches, and beverages for breaks. A discounted registration fee of $90 is being offered to those who register by Thursday, April 1, 1999.

If you need special accommodations due to a disability, please contact Gustavo Godoy, Executive Director and Administrative Officer for R&D, VA Medical Center, 1201 NW. 16th St., Miami, FL 33125, 305–324–3179, FAX 305–324–3126, at least 7 days in advance.

Dated: March 19, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–7361 Filed 3–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0484]

Draft Guidance for Industry on Accelerated Approval Products: Submission of Promotional Materials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Accelerated Approval Products: Submission of Promotional Materials.'' The accelerated approval regulations require that applicants, unless otherwise informed by the agency, submit to FDA for consideration during the preapproval review period copies of all promotional materials, including promotional labeling and advertisements, intended for dissemination or publication within 120 days following marketing approval. This draft guidance is intended to assist sponsors of drug and biological products who are submitting such materials as part of the accelerated approval process.